August 27, 2002

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
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CITIZEN PETITION

The undersigned submits this petition under 21 CFR 10.25(a) and 10.30, and pursuant to 21 CFR 314.161 to request the Commissioner of Food and Drugs to make a prompt determination as to whether a listed drug that has been voluntarily withdrawn from sale in the United States was withdrawn for reasons other than safety or effectiveness.

A. ACTION REQUESTED

According to publicly available reports, Allergan, Inc. (Allergan) has voluntarily withdrawn its drug ALPHAGAN® (brimonidine tartrate ophthalmic solution) 0.2% (NDA 20-613) from sale.

The undersigned is seeking a determination by the Commissioner of the Food and Drug Administration (FDA) that Allergan's voluntary withdrawal from sale of ALPHAGAN® was for reasons other than safety or effectiveness, and that ALPHAGAN® 0.2% may therefore continue to be relied upon as a reference listed drug in abbreviated new drug applications (ANDAs).

The undersigned requests that the Commissioner make an expeditious determination that ALPHAGAN® was not voluntarily withdrawn from sale for safety or effectiveness reasons.

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B. STATEMENT OF GROUNDS

ALPHAGAN® (brimonidine tartrate ophthalmic solution) 0.2% is currently listed in FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the Orange Book) in the Prescription Drug Product List section as NDA 20-613 (see Appendix 1) and as a reference listed drug. This listing indicates that the specific drug product is the subject of an approved application, and that it may be referenced as a listed drug in ANDAs.

Notwithstanding the listing of ALPHAGAN® in the Orange Book , on July 2, 2002, Allergan issued a press release stating their plans to discontinue all U.S. distribution of ALPHAGAN® (brimonidine tartrate ophthalmic solution) 0.2% (see Appendix 2). Furthermore, on July 24, 2002, during Allergan's 2002 Quarterly public Conference Call, when questioned by an analyst regarding ongoing litigation involving ALPHAGAN® and the continued distribution of ALPHAGAN® (brimonidine tartrate ophthalmic solution) 0.2%, the President of Allergan, David E. I. Pyott, responded that the litigation would not be so much of an issue going forward as they were withdrawing ALPHAGAN® (brimonidine tartrate ophthalmic solution) 0.2% from the market and had accomplished a stock replacement with ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.15%.

Publicly available information indicates that Allergan did not withdraw ALPHAGAN® from the market due to any safety or effectiveness reasons. To the contrary, all indications are that the withdrawal was undertaken voluntarily and for reasons of business and market strategy. In fact, some eight months ago, Allergan itself relied on ALPHAGAN® to obtain approval of its new drug ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.15% (NDA 21-262). The FDA Review Packet (Summary Basis of Approval) for NDA 21-262, ALPHAGAN® P (brimonidine tartrate ophthalmic solution) 0.15%, details that the basis for approval of the new product was its therapeutic equivalence to ALPHAGAN® (brimonidine tartrate ophthalmic solution) 0.2% (see Appendix 3). This approval of ALPHAGAN® P based in part on ALPHAGAN® shows that there are no meaningful safety or effectiveness concerns related to ALPHAGAN®.

The absence of safety or effectiveness concerns related to ALPHAGAN® is confirmed by available adverse event information. A search of the FDA Safety and Adverse Event

Reporting Program (Medwatch) website for ALPHAGAN® (brimonidine tartrate ophthalmic solution) 0.2% revealed only two changes to the package insert, one on December 13,1999 with the addition of adverse events to the "Pediatric Use" section of the package insert, and a second on December 20, 2001 again to the "Pediatric Use" section of the package insert, this time reporting the results of a well-controlled clinical study (see Appendix 4). Accordingly, available data through Medwatch further demonstrates that there are not existing safety or effectiveness concerns that led to the withdrawal of ALPHAGAN® from the market.

Under FDA regulations, an approved drug is removed from the Orange Book (de-listed) if the Agency withdraws or suspends approval of the drug's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an abbreviated new drug application (ANDA) that references the listed drug may be approved (21 CFR 314.161(a)(1)).

As stated previously, ALPHAGAN® (brimonidine tartrate ophthalmic solution) 0.2% was approved for safety and effectiveness by the FDA. If the approved product was not withdrawn from the market for safety or effectiveness reasons, the product should still be considered a reference listed drug for the purpose of submitting an ANDA. Therefore, because the NDA holder has discontinued marketing of this drug product, petitioner requests that FDA determine whether the decision to discontinue marketing of the product, approved under NDA 20-613, was for reasons of safety or effectiveness. All available evidence indicates that the voluntary withdrawal from sale of ALPHAGAN® (brimonidine tartrate ophthalmic solution) 0.2% was strictly an economic/strategic decision by Allergan, totally unrelated to safety or efficacy, and that the product may still be referenced as a listed drug in ANDAs. FDA should make the determination that the voluntary withdrawal was not for safety and effectiveness reasons, and we request that ALPHAGAN® be listed in the discontinued section of the Orange Book and allow for reference to ALPHAGAN® as a listed drug.

Petitioner further requests that the Commissioner make this determination expeditiously, either on the agency's own initiative or in response to this petition, pursuant to 21 CFR 314.161(a). Petitioner has a pending ANDA that was submitted prior to the voluntary withdrawal from sale of the listed drug ALPHAGAN®. The public interest and fundamental fairness support expeditious action in this case.

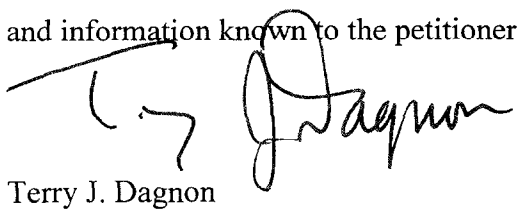
For the forgoing reasons, the petitioner respectfully requests that the Commissioner take the requested action as soon as possible.

C. ENVIRONMENTAL IMPACT STATEMENT

A claim for categorical exclusion of the requirement for submission of an environmental assessment is made pursuant to 21 CFR 25.31.

D. CERTIFICATION

The undersigned certifies that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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